K132545

510(k) Summary
MediValve acWire

Submitter:	MediValve Ltd. Misgav Venture Accelerator Misgav Business Park 17 Tchelet Street M.P. Misgav 20174, Israel Tel: +972.72.260.7000
Contact Person:	Leo Basta NorthStar Biomedical Associates 93 Benefit Street Providence, RI, 02904 Phone: 617.834.9866 lbasta@northstarbiomedical.com
Date Prepared:	August 9, 2013
Trade Name:	MediValve acWire
Classification Name:	catheter, guide, wire
Regulation Number:	21 CFR 870.1330
Product Code:	DQX
Predicate Devices:	Ostial Pro Stent Positioning System (K062192) Lake Region Manufacuring (LRM) Catheter Guidewire (K011084)
Device Description:	The acWire device is a 0.035'' outside diameter, single use, disposable guidewire. The acWire device consists of a flexible guidewire that incorporates a low profile, radiopaque alignment element consisting of three loops with radiopaque markers that when open, form a "tulip" configuration designed to assist the physician in acquiring a reference plane under fluoroscopy.

NOV 0 8 2013

Intended Use: Intended to facilitate the delivery of catheter-based interventional devices in the cardiovascular system

Indications for Use: The acWire is intended for use in peripheral vascular and heart catheterization procedures to introduce and assist in positioning diagnostic and interventional devices. The acWire may also function as an alignment tool by providing a reference plane of anatomical structures of interest (e.g., the aortic valve).

Functional Testing:

Descriptive information, laboratory bench testing, and biocompatibility testing were provided to demonstrate the device meets its design specifications, performs as intended, and is safe for its intended use. Specifically, safety of the acWire device was evaluated through design verification testing including the following:

- Tip Flexibility
- Torque Testing
- Torque Strength
- Fracture Test
- Resistance to Coating Damage
- Coating Adhesion
- Particulate Residual
- Tensile Testing
- Repeated Use Test
- Corrosion Test
- Shelf-Life Test
- Radiopacity Test
- Loop Deflection Test
- Usability Test
- Stiffness Test
- Compatibility Test
- Austenite Finish Test
- Ex-vivo Performance Test

Additionally, biocompatibility testing was performed in accordance with ISO 10993-1 and included the following tests:

- Cytotoxicity Study
- Maximization Sensitization
- Intracutaneous Study
- Systemic Toxicity Study

- Pyrogen Study - Material Mediated
- Hemolysis
- In Vivo Thromboresistance Study
- SC5b-9 Complement Activation Assay
- C3a Complement Activation Assay

The collective results have demonstrated that the acWire device is safe and is substantially equivalent to the respective predicate devices with regard to safety and effectiveness. Any differences in technological characteristics between the acWire device and the predicate devices do not raise any new issues of safety or effectiveness.

Technological Characteristics:

Both the acWire and the Ostial Pro include an alignment element with alignment functionality. Both the acWire's and Ostial Pro's alignment element are made using the same materials. The acWire device is 0.035'' diameter, as is the Lake Region guidewire, while the Ostial Pro is 0.018'' inches in diameter. Both the acWire and Lake Region devices consist of a stainless steel core and coil with a PTFE coating. Any differences in the technological characteristics between the acWire and its predicate devices do not raise any new issues of safety or effectiveness. The performance as evaluated in bench tests, demonstrates that the acWire device is as safe and effective as the predicate devices.

Summary of Substantial Equivalence:

The design, intended use, principles of operation, and technological characteristics of the acWire are substantially equivalent to those of the predicate devices cited above. Substantial equivalence is based upon descriptive characteristics of the various cited predicate devices and upon the testing conducted to demonstrate that the subject device performs as intended and is substantially equivalent to the predicate devices in terms of its ability to safely perform as a cardiovascular guide wire. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the acWire device is substantially equivalent to the predicates devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 8, 2013

Medivalve Ltd.
% Leo Basta
NorthStar Biomedical Associates
93 Benefit Street
Providence, RI 02904

Re: K132545
Trade/Device Name: Medivalve acWire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter, Guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: October 25, 2013
Received: October 28, 2013

Dear Mr. Basta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K132545

Device Name: MediValve acWire

Indications for Use:

The acWire is intended for use in peripheral vascular and heart catheterization procedures to introduce and assist in positioning diagnostic and interventional devices. The acWire may also function as an alignment tool by providing a reference plane of anatomical structures of interest (e.g., the aortic valve).

Prescription Use: X AND/OR Over-The Counter Use: _____
(Per 21 CFR 801 Subpart D)..... (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1